**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| APPLICANT | : | David BASSIN |
| SERIAL NO. | : | 10/596,034 |
| FILING DATE | : | January 31, 2007 |
| GROUP ART | : | 4177 |
| EXAMINER | : | LOUIS, Latoya M |
| TITLE | : | METHODS AND APPARATUS FOR THE SYSTEMATIC CONTROL OF VENTILATORY SUPPORT IN THE PRESENCE OF RESPIRATORY INSUFFICIENCY |

**REQUEST FOR CONTINUING EXAMINATION UNDER 37 C.F.R. § 1.114**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is in response to the Advisory Action of June 9, 2010.

The **Claims** Section begins on page 2 of this paper.

The **Remarks** begin on page 9 of this paper.

## CLAIMS

112. (Currently Amended) Apparatus for providing ventilatory pressure support ~~assistance~~ to a patient comprising

a control mechanism for deriving two calculated errors ~~error signals~~

each of which is a function of the same target ventilation value and a respective one of two patient ventilation measures,

the two patient ventilation measures having respective relatively fast and relatively slow speeds of response to said calculated errors,

said control mechanism further deriving two control responses of pressure to respective ones of said two calculated errors ~~error signals~~ and combining said two control responses to produce an overall control response that increasingly favors the control response to the calculated error ~~signal~~ that is a function of the ventilation measure with the faster speed of response over the control response to the calculated error ~~signal~~ that is a function of the ventilation measure with the slower speed of response as the ventilation measure with the faster speed of response becomes increasingly less than said target ventilation value; and a ventilator responsive to said overall control response for controlling the level of pressure of air delivered to said patient.

113. (Currently Amended) Apparatus for providing ventilatory pressure support ~~assistance~~ to a patient in accordance with claim 112 wherein each of said two control responses is a function of the amplitude and sign of the

respective one of said calculated errors ~~error signals~~ so that the control response to the calculated error ~~signal~~ that is a function of the ventilation measure with the faster speed of response is more vigorous than the control response to the calculated error ~~signal~~ that is a function of the ventilation measure with the slower speed of response.

114. (Currently Amended) Apparatus for providing ventilatory pressure support ~~assistance~~ to a patient in accordance with claim 113 wherein the degree of control exercised by said ventilator increases with the magnitudes of said two calculated errors ~~error signals~~.

115. (Currently Amended) Apparatus for providing ventilatory pressure support ~~assistance~~ to a patient in accordance with claim 114 wherein for equal calculated errors ~~error signals~~ below and above said target value, the degree of control exercised by said ventilator is greater for calculated errors ~~error signals~~ below said target value.

116. (Currently Amended) Apparatus for providing ventilatory pressure support ~~assistance~~ to a patient in accordance with claim 115 wherein said target value is an alveolar ventilation that takes into account the patient's anatomical or physiologic dead space.

117. (Currently Amended) Apparatus for providing ventilatory pressure support ~~assistance~~ to a patient in accordance with claim 116 wherein said control mechanism further determines the phase of the current breathing cycle and adjusts said overall control response to be a function of the amplitude at the determined phase of the current breathing cycle of an amplitude-versus-phase template that is appropriate for a normal breathing cycle.

118. (Currently Amended) Apparatus for providing ventilatory pressure support ~~assistance~~ to a patient in accordance with claim 117 wherein said control mechanism determines the phase of the current breathing cycle by relating respiratory airflow and its rate of change to different phases of a normal breathing cycle.

119. (Currently Amended) Apparatus for providing ventilatory pressure support ~~assistance~~ to a patient in accordance with claim 118 wherein said control mechanism determines the phase of the current breathing cycle by applying a set of fuzzy logic rules.

120. (Currently Amended) Apparatus for providing ventilatory pressure support ~~assistance~~ to a patient in accordance with claim 119 wherein said overall control response is a clipped integral of a function of both of said calculated errors ~~error signals~~.

121. (Currently Amended) Apparatus for providing ventilatory pressure support ~~assistance~~ to a patient in accordance with claim 112 wherein the degree of control exercised by said ventilator increases with the magnitudes of said two calculated errors ~~error signals~~.

122. (Currently Amended) Apparatus for providing ventilatory pressure support ~~assistance~~ to a patient in accordance with claim 121 wherein for equal calculated errors ~~error signals~~ below and above said target value, the degree of control exercised by said ventilator is greater for calculated errors ~~error signals~~ below said target value.

123. (Currently Amended) Apparatus for providing ventilatory pressure support ~~assistance~~ to a patient in accordance with claim 122 wherein said target value is an alveolar ventilation that takes into account the patient's physiologic dead space.

124. (Currently Amended) Apparatus for providing ventilatory pressure support ~~assistance~~ to a patient in accordance with claim 112 wherein said target value is an alveolar ventilation that takes into account the patient's physiologic dead space.

125. (Currently Amended) Apparatus for providing ventilatory pressure support ~~assistance~~ to a patient in accordance with claim 112 wherein said control mechanism further determines the phase of the current breathing cycle and adjusts said overall control response to be a function of the amplitude at the determined phase of the current breathing cycle of an amplitude-versus-phase template that is appropriate for a normal breathing cycle.

126. (Currently Amended) Apparatus for providing ventilatory pressure support ~~assistance~~ to a patient in accordance with claim 125 wherein said control mechanism determines the phase of the current breathing cycle by relating respiratory airflow and its rate of change to different phases of a normal breathing cycle.

127. (Currently Amended) Apparatus for providing ventilatory pressure support ~~assistance~~ to a patient in accordance with claim 126 wherein said control mechanism determines the phase of the current breathing cycle by applying a set of fuzzy logic rules.

128. (Currently Amended) Apparatus for providing ventilatory pressure support ~~assistance~~ to a patient in accordance with claim 112 wherein each of said calculated errors ~~error signals~~ is a clipped integral of the respective patient ventilation measure minus said target value.

129. (Currently Amended) Apparatus for providing ventilatory pressure support ~~assistance~~ to a patient in accordance with claim 112 wherein said ventilator includes a servo control mechanism whose gain is adjusted in accordance with the magnitudes of said calculated errors ~~error signals~~.

130. (Currently Amended) Apparatus for providing ventilatory pressure support ~~assistance~~ to a patient in accordance with claim 129 wherein said gain increases with the magnitudes of said calculated errors ~~error signals~~.

131. (Currently Amended) Apparatus for providing ventilatory pressure support ~~assistance~~ to a patient in accordance with claim 130 wherein for equal calculated errors ~~error signals~~ below and above said target value, said gain is greater for calculated errors ~~error signals~~ below said target value.

132. (Currently Amended) Apparatus for providing ventilatory pressure support ~~assistance~~ to a patient in accordance with claim 130 wherein said gain is varied more aggressively for conditions of hypoventilation than for conditions of hyperventilation.

133. (Currently Amended) Apparatus for providing ventilatory pressure support ~~assistance~~ to a patient in accordance with claim 112 wherein said ventilator is flow-triggered and phase cycled.

134. (Currently Amended) Apparatus for providing ventilatory pressure support ~~assistance~~ to a patient in accordance with claim 112 wherein said ventilator withdraws ventilation support more gradually when the patient is over-ventilated than when the patient is under-ventilated.

## REMARKS

Applicant expresses appreciation for the interview of July 21, 2010 where discussion centered on a single cited reference, U.S. Patent No. 5,645,054 to Cotner et al. ("Cotner"), and how the present invention is believed not to be anticipated by Cotner and not unpatentable in view of Cotner.

Claims 112-134 are pending in the present application. The Applicant understands that the earlier response, dated May 21, 2010, was not entered by the Examiner, so much of the presented argument is included in this response. That response was provided in order to overcome the Final Office Action mailed on March 18, 2010. Based upon that Office Action, claims 112-114 and 121 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Cotner. Claims 115, 122, 125, and 128-134 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Cotner in view of U.S. Patent No. 6,951,217 to Berthon-Jones ("Berthon-Jones '217"). Claim 124 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Cotner in view of the article entitled "An Adaptive Lung Ventilation Controller" (of record) by Laubscher et al. ("Laubscher"). Claims 116, 117, and 123 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Cotner and Berthon-Jones '217 as applied to claims 115 and 122 above, and further in view of Laubscher. Claims 126 and 127 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Cotner and Berthon-Jones '217 as applied to claims 125 above, and further in view of U.S. Patent No. 6,532,957 to Berthon-Jones ("Berthon-Jones '957"). Claims 118-120 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Cotner, Berthon-Jones '217, and Laubscher as applied to claims 116 and 117 above, and further in view of Berthon-Jones '957. In

summary, all claims stand rejected at least in part on Cotner. As detailed below, Cotner does not disclose or suggest much of claim 112, such as but not limited to the two calculated errors and the selection algorithm.

The present amendment includes several changes from the most recently entered amendment in part to address comments raised in the Advisory Action mailed on June 6, 2010 and the interview of July 21, 2010. The word "ventilation" is being added to claim 112 for consistency with the specification and to make clear that the value of interest is a <u>ventilation</u> value. The words "pressure support" replace the word "assistance" in all claims for consistency with the wording in the specification. The words "level of" are added in claim 112 for clarity and to better define the word "pressure". Other words are added in claim 112 in response to particular items identified in the continuation sheet within the Advisory Action.

Also, in several claims, the term "error signal(s)" is being replaced with "calculated error(s)" to more clearly identify that at least one calculation of an error is performed rather than a signal being identified. This change is consistent with the discussion at the interview whereby the Examiner noted that the broadness of the word "signal" may cause the present application to appear to be similar in at least some ways to Cotner.

The single independent claim (claim 112) in the application defines two calculated ventilation errors, each of which is a function of the same target ventilation value and a respective one of two ventilation measures. The two ventilation measures have different speeds of response. The claim goes on to define implementation of an algorithm in which the two control responses are combined and when each control

response is favored so that it has a greater effect on the overall pressure control response.

The main reference cited by the Examiner is Cotner. As will be discussed in detail below, Cotner describes a system which (1) determines the lack of patient breathing, (2) does not "measure" patient breathing as the term is used in the present invention (a determined volume of air over time), (3) contains at most one error signal, not two as asserted by the Examiner, (4) also does not calculate error at all, and (5) any selection algorithm it might include, even assuming it does make a selection, is completely different from the one in the present claims. The Cotner system does not have even one ventilation measure and, as compared with claim 112, does not have different speeds of response. Cotner therefore cannot possibly have a mechanism for choosing one response speed over the other. The single independent claim in issue has little to do with Cotner.

In the Office Action mailed March 18, 2010, the Examiner states "normal inhalation as a target value". Not only is the statement unclear as to which element of Cotner the Examiner equates to the claimed target ventilation, but there is in fact nothing in Cotner that could even be the claimed target ventilation. Neither of the signals M and R can be the claimed target ventilation, first because neither represents ventilation, and second because both are measures of the actual behavior of the patient, as opposed to a target behavior that a servo-controller seeks to produce in the patient. The signal M is a pressure measurement, not a target value and not a ventilation quantity, and the signal R is simply a time-lagging M signal.

The Examiner refers to the two signals M and R shown in Fig. 2a of Cotner and seems to treat the Cotner system as a type of servo whose output is governed by an input, with the output being controlled by an error signal that is dependent on the difference between the output and the input. But not only are signals M and R not measures of ventilation, calculated ventilation error, or ventilation error, in Cotner neither signal M nor signal R is even any kind of measure of error. One signal is simply a delayed version of the other and they do not have anything resembling a servo relationship.

Furthermore, the control response stated in claim 112, the only independent claim in the application, is the control of pressure. The faster speed of response results in a change of pressure that is faster than the change in pressure that results from the slower speed of response. There is nothing in Cotner about different rates at which the pressure is changed.

An important thing to observe about claim 112 is the symmetry that is maintained. There are two calculated errors, each of which is based on a different ventilation measure. Each ventilation measure is characterized by a speed of response. There are two control responses (to respective ones of the two error calculations). The claim defines which control response is favored under which conditions, but the control responses are independent and comparable. In Cotner, signals M and R cannot possibly be comparable in the sense of responding to events independently and controlling responses independently since signal R is derived directly from signal M. Signal R is simply a filtered version of signal M.

In the Cotner system, what the Examiner calls two error signals and two control responses are very different, even according to the way that the Examiner described them. As we shall see, the two of them are not even remotely comparable. There is really only one error signal and one control response in Cotner. What the Examiner denominates as the second error signal and control response are nothing more than a circuit to make sure that the single error signal circuit operates properly (by not allowing a short breath to be interpreted as a normal breath).

In Cotner, sensor 28 is called a flow sensor, although the output is actually a pressure signal. The signal is fed directly through filter 23 to a first input of comparator 24. The signal is also fed to "dynamic reference tracking circuit" 25. In a previous response filed by Applicant it was said that this filter circuit derives an average value of the sensor signal. On page 13 of the Office Action mailed March 18, 2010, the Examiner explains that the circuit simply delays the sensor signal. Both descriptions are correct. The output of a low-pass filter <u>is</u> a moving near-term average of the filter's input signal.

The delayed signal is fed to the second input of the comparator. When the sensor signal is increasing, the signal at the first input of the comparator is greater than the delayed signal at the second input. For this condition, the comparator output remains low.

But when the breathing phase changes, the current signal drops below the delayed signal, and the comparator output goes high. If the patient's airway is open, then the comparator output goes high during every breath. If there is no high output for 8 seconds Cotner assumes there is no breath because this 8 second gap is considered

to be an indication of a closed airway. Cotner then increases the pressure. What is important regarding the present invention is that even if Cotner describes the circuit as an error circuit, it is only determining the absence of an output pulse for 8 seconds so as to identify if the patient's airway is closed. It is not measuring or calculating anything and is not comparing anything to a target.

If the patient's airway narrows right after the start of a breath, the comparator will generate a very short positive pulse as shown in Fig. 2b (the reference is to the second pulse on the horizontal axis). This short pulse is said to be indicative of a less-than-full breath, and it should not restart the 8-second timing cycle in progress. So the circuit is designed to ignore the short pulse (i.e., not to recognize it during the 8-second interval during which the absence of a pulse indicates the need for corrective action by increasing the pressure). The antifalsing circuit 17, a filter, gets rid of the short blip so that it is not recognized as representing a breath.

The antifalsing circuit thus simply insures that the single circuit that is said to recognize an airway closing operates to detect only breaths that exceed a certain minimum duration. The antifalsing circuit is not in some kind of control loop for controlling a response to anything. Recall that it is positive pulses at the output of the comparator that indicate airflow, that is, as long as there is a comparator output pulse at least every 8 seconds, it is assumed that there is no problem. Cotner states that "[t]he circuit 17 slow[s] down the output of the differential operational amplifier [comparator] in the inhalation detector 24 to prevent short duration pulses, which characterize 'critical flow limitations' (reduced inhalation), from being sensed as normal inhalation." (col. 6, ln. 59-64).

In short, even if the absence of a pulse for 8 seconds is considered to be an "error signal" (a very expansive interpretation of the term "error signal"), there would still be only one error signal and <u>zero</u> calculated errors in Cotner to control a change in pressure, not two. Again, even if there is an error signal, it is an indicator of whether the patient is breathing and not a calculated or quantified difference from a target. As for the claimed "target value," what the Examiner has selected in Cotner for this parameter will be discussed below, but since there is at most only one error signal, it follows that there cannot possibly be two error signals that are both functions of the same target value as the claim requires. Even if there is a ventilation measure (it is not clear what it would be) in Cotner, there would be only one, not two. There is only one speed of response, not two. Since there is at most only one error signal, not two, it is meaningless to talk about one control response being favored over the other in Cotner, and it is certainly meaningless to talk about how the favoritism changes. There is practically nothing in the independent claim in issue that applies to the reference.

With regard to the Examiner's analysis of the reference circuit, column 6-8 of Cotner describes an error control (once again, only with an expansive interpretation of "error"), as the Examiner indicates on page 2 of the Office Action. But column 6, lines 56-64, and column 8, lines 11-26 and 42-60, do not describe a second error control signal. This material describes how the antifalsing circuit simply prevents erroneous operation of the single error control circuit. What the Examiner is calling a second error signal does not control a pressure change. Rather, it is included in the circuit "to prevent short duration pulses ... from being sensed as normal inhalation." And the material in column 8 identified by the Examiner is equally explicit:

> FIG. 2C shows how the time delay in the antifalsing circuit 17 modifies the signal sent to the timing circuit 27 by delaying the leading edge "E" of the square wave and totally eliminating the false inhalation detection wave "P" indicated in FIG. 2b.

The Examiner's "second error signal" eliminates false inhalation detection (short breaths), but is not a signal that is in competition for control with a first error signal, and there are no rules for deciding which of two signals is favored.

In addition, Cotner does not include a "target ventilation value". On page 2 of the Office Action mailed on March 18, 2010, the Examiner considers the "target ventilation value" of the claim as corresponding to "normal inhalation" in Cotner. The target ventilation value of the claim means a desired volume of air delivered over a period of time to be used for comparing to actual measured volumes of air over a period of time. The so-called target value in Cotner, according to the Examiner, is nothing more than a breath at least once every 8 seconds. This 8 second gap would not be considered a target volume of delivered air, as the target is called for by the claim.

The Examiner next considers the two ventilation measures of the claim and identifies column 6, lines 44-67, as referencing "the output of flow sensor 28 and the output of dynamic reference circuit 25 as two ventilation measures." But in fact the two outputs are based on the same flow measure. It is just that one is filtered and lags the other. (See column 6, lines 22-24.) There is at most only one ventilation measure in Cotner, and it is the output of the flow sensor (and even that is not "measured"). It is improper for the Examiner to take sequential signals in a processing chain and to say that they are different ventilation measures when in fact they are based on only a single signal.

Because there is at most one signal in Cotner, there cannot be two different response speeds (as stated in the Office Action). Cotner column 6, lines 13-30, just does not support two different response speeds and there is no other support in this material for the argument. The citation merely states that the output of flow sensor 28 feeds the input of dynamic reference circuit 25 (through filter 23), and does not even suggest two different response speeds. The output of one cannot get increasingly ahead of or behind the other if circuit 25 simply delays the output of circuit 28. A response speed is how fast the response of a control circuit is to an input that represents an error. The two signals identified by the Examiner do not even represent errors, so they cannot have response speeds and they most certainly cannot have <u>different</u> response speeds. One output represents flow, and the other represents flow delayed in time. There is no error here to even speak of. An error indication (not even a calculated error or an error signal) occurs only later in the chain when comparator 24 operates and does not output a pulse for 8 seconds. The two outputs of circuits 28 and 25 do not represent errors of any kind, so they cannot possibly have different response speeds since they don't have response speeds.

Fig. 2a in Cotner shows two curves, the output of the flow sensor (the "M" solid curve) and the output of the dynamic reference circuit (the "R" dashed curve). It is obvious that the latter is delayed from the former as the result of filtering. The Examiner refers to the two outputs as supporting the assertion that they have fast and slow response speeds respectively, but the two curves have nothing to do with response speeds. One signal is used to make sure that the other does not cause a false inhalation pulse to be recognized, and neither even represents an error for which there

could be a response. An "error" is not detected until later on in the processing chain, when an inhalation pulse is absent for 8 seconds.

The Examiner's analysis on page 3 of the Office Action regarding Fig. 3 of Cotner and the description at column 9, lines 64 through column 10, line 2, and column 9, lines 12-18, also does not conform to what the reference patent actually teaches. Fig. 3 shows how a low mask pressure at the onset of a critical flow limitation (point C, what might be considered an "error") persists for only 8 seconds, at which time (point D) the pressure starts to rise. The Examiner translates this into point C representing a second error signal to keep the pressure low, and point D representing the first error signal at which time the pressure goes higher, with the two control responses being combined to produce an overall response that favors increasing the pressure in response to the error signal that is a function of the ventilation measure with the faster speed of response as the ventilation measure with the faster speed of response becomes increasingly less than the target value. But all that Fig. 3 in Cotner et al. actually shows is how the pressure changes, with the interval from C to D simply showing that the pressure does not start to rise until inhalation has not been detected for 8 seconds. The figure has nothing to do with different ventilation measures, different control responses, favoring one control response over another, target values or any of the other things the Examiner has read into the drawing and description.

On page 4 of the Office Action, the Examiner turns to the dependent claims. Contrary to what the Examiner says with reference to claim 113, Cotner does not have two control responses as previously discussed, and there is no such thing as one response being more vigorous than the other. Causing blower speed (pressure) to

increase may be more vigorous than causing it to remain constant, as the Examiner asserts. But keeping the pressure constant means that there is no error; and, if there is no error then there is no response to speak of. There is no getting away from the fact that in Cotner there is just one "error" (no inhalation for 8 seconds), and there is just one control response (increase the pressure until there is inhalation).

Similar remarks apply to claims 114 and 121, the rejection of which is once again based on the erroneous supposition that Cotner disclose two ventilation measures, two error signals, two control responses, and a way to favor one control response over the other.

Starting on page 5 of the Office Action, the Examiner combines Cotner with two secondary references in rejecting some of the dependent claims under Section 103. That some of the features added by the dependent claims may be disclosed in the secondary references is of little moment since the basic control structure is not disclosed or suggested by Cotner or any of the secondary references.

On page 12 of the present Office Action the Examiner identifies two error signals and disputes the earlier argument which said that there is just one error signal. The end of the 8-second timing interval is said to be the first error signal, and the second error signal is said to be the critical flow limitation that indicates reduced inhalation and that is described at column 6, line 63, and column 8, lines 12-13.

Referring to column 8, lines 12-13, it appears that what the Examiner refers to as the second error signal is at point 5 in Figs. 2a and 2b. And it is here that the Examiner has analyzed Cotner incorrectly. Referring to Figs. 2a and 2b, point 5 represents the

same kind of "error" signal as point 1. Both points represent the same kind of change in breathing phase. Referring to Fig. 2a, it will be seen that at both points the solid line M and the dashed line R intersect, with the solid line going down past the dashed line. But because the second breath shown by curve M in Fig. 2a is so short, it is not considered to be a breath and should not start the 8-second timer all over again. What the Examiner is calling the second error circuit (the dynamic reference tracking circuit 25) eliminates the effect of the short pulse in Fig. 2b. This is shown in Fig. 2c where the short pulse (representing a short breath that is to be ignored by the single error-detecting circuit) is missing. Thus rather than the purported second error signal having an effect similar to that of the first error signal (and satisfying the symmetrical structure of claim 112), the second signal has the opposite effect. Every pulse from the first error circuit starts the timer all over again. The second error circuit is designed to prevent pulses at the output of the first error circuit from restarting the timer. The key sentence in the Office Action is the following at page 12:

> Therefore, the signal or indication that 8 seconds have elapsed as [sic] first error signal, and the signal or indication of a critical flow limitation are two different signals indicating a deviation from proper inhalation and both are used to control the ventilator.

This is wrong because there is only one kind of error detection in Cotner -- the absence of inhalation for 8 seconds. The Examiner's second "error" signal prevents a short breath from being treated as a breath (because it is not considered to be a breath), but there is still only one kind of error detection. And certainly there is nothing in the circuit that favors one signal over the other when one signal simply modifies the other. And since the second signal controls nothing on its own, but simply affects the first signal, it

makes no sense to apply the claim and say that there is a speed of response that applies to the second signal.

It is believed that claims 112-134 are in a condition for allowance, and the early passage to issue of the application is respectfully requested.

If any additional fee is required, the Commissioner is hereby authorized to charge the amount of any such fee to Deposit Account No. 07-1730, Docket No. 3869-029.

Respectfully submitted,
**GOTTLIEB, RACKMAN & REISMAN**

Barry R. Lewin
Reg. No. 64,223
Attorney for Applicant
270 Madison Avenue, 8th Floor
New York, NY 10016
(212) 684-3900
blewin@grr.com

**Dated:** August 11, 2010

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